UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,713	07/22/2002	Carl V. Manion	11146/11005	7559

7590 05/07/2004

Eugenia S Hansen
Sidley Austin Brown & Wood
Suite 3400
717 N Hardwood
Dallas, TX 75201

EXAMINER	
PAK, JOHN D	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 05/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/088,713	MANION, CARL V.	
	Examiner	Art Unit	
	JOHN D PAK	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-16* is/are pending in the application.

4a) Of the above claim(s) *6-11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-5 and 12-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 3-16 are pending in this application. Claims 6-11 stand withdrawn from further consideration as being directed to non-elected inventions. Claims 3-5 and 12-16 will presently be examined.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 3-5 and 12-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8-15 of U.S. Patent No. 6,384,076. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

Claims 8-15 of the cited patent are directed to a method for treatment of sickle cell disease in a patient comprising administering compounds that are the same as those used in applicant's claims (R in the patented claims are narrower but still clearly within applicant's claims). The therapy reduces the capacity of red blood cells in the

patient to sickle (claim 8) and the effective amount is 1.5 to 6 mg/kg of body weight (claim 9).

The patented claims do not expressly state that sickle cell disease is a disease characterized by high whole blood viscosity or abnormally viscous whole blood. However, applicant's own specification admits that sickle cell diseases produce multi-stranded fibers that force a red blood cell into a crescent or sickle shape, which decreases hemoglobin concentration and results in increased whole blood viscosity (p. 1, last paragraph; Fig. 3; Example 1 on p. 9). Therefore, applicant's claim language is readable on treating sickle cell disease. Consequently, applicant's claims would have been recognized as an obvious variation of the patented claims by the ordinary skilled artisan in this field, who is a highly trained medical professional.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> **A person shall be entitled to a patent unless –**
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3-5, 12-16 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 98/13062 (Edmundson et al.).

Edmundson et al. explicitly disclose a method for treating various forms of arthritis such as rheumatoid arthritis by administering the same APM and alkyl ester

derivatives. See claims 17-20. 1.5 –3 mg/kg body weight is disclosed for rheumatoid arthritis treatment. See claims 18-20.

It is recognized that the disclosure by Edmundson et al. does not state in verbatim language a treatment of patients having a disease characterized by high whole blood viscosity or abnormally viscous whole blood. The issue then is whether the patients treated by Edmundson et al. inherently or necessarily had high whole viscosity or abnormally viscous whole blood.

Applicant admits in the specification that patients with arthritis "may exhibit increased whole blood viscosity" (p. 1, lines 20-21). Medline abstracts 90333175 and 93088234 establish that patients with rheumatoid arthritis have higher blood viscosity; Medline abstract 95072271 establish that patients with rheumatoid arthritis have "significantly higher" blood viscosity. Note, these abstracts are discussed only to show what would have been inherent in Edmundson's claims and disclosure, i.e. Edmundson's treated all rheumatoid arthritic patients, and at least some of them must necessarily have had high whole blood viscosity or abnormally viscous whole blood.

Therefore, because the same patients were treated with the same APM and alkyl ester derivatives with the same dosage, the same therapeutic result, i.e. reduction in whole blood viscosity in a patient, must necessarily have been obtained. The claims are anticipated.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620, effective February 3, 2004.** The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Thurman Page, can be reached on (571)272-0602, effective February 3, 2004.

The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

JOHN PAK
PRIMARY EXAMINER
GROUP 1600